UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FILE

NOV 14 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: *OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE REREGISTRATION OF MERIT (AI IMIDACLOPRID) ON TURF*

FROM: Leo LaSota, Ph.D., Biologist
Special Review and Registration Section II
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

TO: Michael Metzger, Chief
Risk Characterization and Analysis Branch
Health Effects Division (7508W)

THRU: Mark Dow, Ph.D., Section Head
Special Review and Registration Section II
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Ed Zager, Acting Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

DP Barcode: D223275

Pesticide Chemical Code: 129099

EPA Reg. No.: 003125-00414

EPA MRID No: 439239-01

I. ACTION REQUESTED

The Special Review and Reregistration Division (SRRD) has requested that the Occupational and Residential Exposure Branch (OREB) review a turf re-entry study in support of the Subdivision K Guideline data requirements for the reregistration of MERIT (active ingredient, imidacloprid) on residential and commercial turf.

II. BACKGROUND

MERIT is an EPA-registered systemic insecticide for insect control in turfgrass and ornamentals. MERIT's specific turf applications are for control of sucking insects, certain weevil and beetle species, and leafminers. The active ingredient in MERIT is: 1-[(Chloro-3-pyridinyl)methyl]-4,5-dihydro-N-nitro-1H-imidazol-2-amine. Imidacloprid is the common name for MERIT. The formulation used in this study was MERIT 2, a 21% liquid flowable (LF) formulation. Other MERIT formulations include a 75 WP and 0.5 granular.

The applicant's general objectives for conducting this study were to:

Generate compound-specific transferable residue data for MERIT used with human exposure data to evaluate potential risks for persons contacting treated turf;

Measure inhalation and dermal exposure experienced during high contact activity on turf;

Calculate a turf-contact dermal transfer factor which can be used with product-specific transferable residue data to estimate similar exposures for other pesticides applied to turf.

The specific guideline Subpart K data requirements addressed in this report are:

132-1(a) Foliar Dislodgeable Residue Dissipation: Lawn and Turf (Series 875 number 852.2100)

133.3 Dermal Exposure (Series 875 number 875.2400)

133.4 Inhalation Exposure (Series 875 number 875.2500)

III. Conclusions and Recommendations

CONCLUSIONS

132-1(a) Foliar Dislodgeable Residue Dissipation: Lawn and Turf

This **study is acceptable, with the recommendations noted below,** in providing the information necessary to calculate the dislodgeable MERIT residues immediately after the spray has dried and the anticipated half-life of MERIT under a range of field conditions.

The residue monitoring portion of the study was done at sites in Florida, New Jersey and Kansas using the maximum label rate of 0.5 AI/acre. A turf roller technique was used to measure dislodgeable (termed "transferable" in the report) MERIT levels at various time increments up to 14 days after application.

Deposition residues were measured on deposition squares at all three sites. These residues averaged 1.4, 2.2 and 2.7 ug/cm^2 in Florida, New Jersey and Kansas, respectively. These values represent approximately 25, 39 and 48%, respectively, of the theoretical target deposition rate for MERIT of 5.6 ug/cm^2 (0.5 lb AI/acre). Absorbent pads were also placed alongside the deposition squares at the Kansas site to determine if MERIT losses were occurring through penetration of the deposition squares. Arbsorbent pad residues indicated a higher deposition rate than reported for the deposition squares: 3.4 ug/cm^2, or 61% of the target value.

Transferable residues collected as soon after application as the spray had dried averaged 35.9, 52.6 and 150.8 ng/cm^2 in Florida, New Jersey and Kansas, respectively. These values represent 3.5, 4.9 and 6.4%, respectively, of the deposited residues measured during application. The combined arithmetic mean MERIT transferable residues for all three study locations was 79.8 ng/cm^2.

An exponential regression analysis was used to determine the **half-life** of MERIT for each turf plot and for the average of all three turf plots. For Florida, the residue decay half-life was approximately 2.0 days; for New Jersey, 0.9 days; and for Kansas, 1.1 days.

RECOMMENDATIONS

1. The 21% liquid flowable (LF) formulation for MERIT was used in this study because it was initially anticipated by the applicant to be the major MERIT product sold for turf. However, the applicant now plans to label the LF MERIT solely for nursery/greenhouse use with MERIT 75 WP and 0.5 G the registered products to be used on turf. The maximum label

rate (0.5 AI/Acre) is the same for the LF, WP and G formulations. Furthermore, both the LF and WP formulations are in the same physicochemical state, an aqueous-based suspension, once they are mixed in the spray tank. For these reasons, OREB believes the LF and WP formulations are comparable in providing a "worst case" scenario for MERIT residue exposure. Conversely, granular-incorporated MERIT would be expected to lodge at the base of turf blades and thus be less available for re-entry dermal contact than would the spray residues.

2. The reentry interval for residential turf is as soon after application as the spray has dried. Calculated half-lives of the LF MERIT formulation used in this study do not address the worst-case scenario which occurs at time zero. **No conclusions can be drawn concerning the anticipated half-life of MERIT granular formulations from the data submitted with this study.**

3. There are deficiencies in the half-life portion of the study which limit the predictive value of the calculations generated from this data. These deficiencies include:

   Inter-site variability in participation;

   Inter-site variability in MERIT deposition levels.

133.3 Dermal Exposure

This study is acceptable as submitted.

The dermal and inhalation exposure portions of the study were conducted at one site (Kansas) only using 10 adult volunteers who performed a choreographed exercise on a turf plot treated with MERIT at the maximum label rate. Dermal levels were measured using whole-body dosimetry. Upper-bound potential exposure data for 5- and 10-year old children were extrapolated from the adult data.

At the Kansas exposure evaluation plot, the reported deposition residues averaged 3.8 ug/cm^2, or 68% of the target rate. The reported transferable residues averaged 74.0 ng/cm^2.

The upper bound **dermal exposure**, using a minimum clothing scenario (MCS) of short pants and a sleeveless shirt, is 131.8 ug/kg/day and 145.8 ug/kg/day for 10-year-old and 5-year-old children, respectively. The no-observable effect level (NOEL) established in a 15-day (6 hours/day X 5 days/week) dermal toxicity study in rabbits was 1,000 mg/day. This results in an upper-bound **margin of safety of 7,587 for 10-year-old and 6,859 for 5-year-old children, respectively.**

Minimum and maximum **dermal transfer factors** (cm^2/hour) were

calculated for both the minimum clothing scenario and the typical clothing scenario (short pants, sleeveless shirt, shoes and socks). Based on these calculations, the upper-bound range of turf-contact dermal transfer coefficients is 1,824-12,426 cm^2/hr for 10-year old children and 1,397-9,212 cm^2/hr for 5-year-old children.

These figures were used in conjunction with the dermal NOEL, average body weight for each group, and a 100-fold safety factor to get an upper bound range of safe exposure levels. **Calculated safe levels ranged from 5.6 to 38.2 ug/cm^2 for 10-year old and 5.1 to 33.5 ug/cm^2 for 5-year old children.** The combined **average MERIT transferable residues levels**, immediately after sprays had dried, at the three test sites **was 0.080 ug/cm^2**. This data indicate that the risks to children are negligible from MERIT-treated turf as soon as the spray has dried.

Reference

A. Study identifier: 1990. NTN 33893 (Proposed Common Name: Imidacloprid) Subacute Inhalation Toxicity Study on the Rat According to OECD Guideline No. 412. Study Number: T7029592. **Report Number: 106463.** Authored by W. Flucke. Performing Laboratory: Bayer AG, Department of Toxicology, Friedrich-Ebert-Str. 217-333, D-56 Wuppertal 1, West Germany (Report No. 100688). **EPA MRID No. 422563-29.**

133.4 Inhalation Exposure

This study is acceptable as submitted.

Inhalation levels were measured using quartz microfibre filters connected by polyvinylchloride tubing to portable air-sampling pumps. The arithmetic and geometric mean MERIT air concentrations measured in the immediate vicinity of the volunteer subjects during performance of their exercise routine were approximately 6.6 (+ or - 2.5) and 6.2 (+ or - 1.5) ug/m^3, respectively. The rat subacute inhalation study (6 hours/day for 20 days) no observable effect concentration (NOEC) for imidacloprid is 5.5 mg/m^3. **This NOEC is approximately 800 times the concentration recorded in the immediate vicinity of volunteers during the performance of their exercise routine.**

Based on the high margin of safety associated with the inhalation readings, and the supporting volatility characteristics of imidacloprid (Vapor Pressure = 6.0 X 10^{-9} Torr.; Henry's 4.0 X 10^{-12} Atm. M^3/Mol), OREB believes the data submitted are sufficient to satisfy Section K 133.4 Inhalation Exposure study requirements.

Reference:

A. Study identifier: 1989. NTN 33893 (Proposed Common Name: Imidacloprid) Subacute Inhalation Toxicity Study on the Rat

According to OECD Guideline No. 412. Study Number: T3027635. **Report Number: 100262.** Authored by J. Pauluhn. Performing Laboratory: Bayer AG, Department of Toxicology, Friedrich-Ebert-Str. 217-333, D-56 Wuppertal 1, West Germany (Report No. 18199). **EPA MRID No. 422730-01.**

IV. DETAILED CONSIDERATIONS

Part I - Foliage Dislodgeable Residue Study

Description of Study Protocol

A. Study identifier: 1994. Evaluation of Potential Exposure Resulting from Contact with MERIT-Treated Turf. Study Number: 92E043. Report Number: 106463. Authored by D.C. Eberhart and G. K. Ellisor, Miles Inc., Agricultural Division, Research and Development Department, 8400 Hawthorn Road, Kansas City, Missouri 64120-0013.

B. Geographical site description: Three test sites, each consisting of one 10 X 40 ft turf plot, were used for the foliar residue study. These plots were the Miles Inc. Research Park in Vero Beach, Florida; the Miles Inc. Research Park in Stilwell, Kansas; and the Rutgers University Turf Research Farm in New Brunswick, New Jersey.

C. Crop Type: The test were conducted on plots containing either St Augustine grass (Florida site) or Kentucky Bluegrass (New Jersey and Kansas sites). **Cultivars were not given.** "Differences in the variety [cultivar], texture and thickness of the grass" could have also contributed to the differences in transferable residues measured between plots immediately after the spray had dried. Uniformity of stand was not asserted. Note the presence of broadleaf weeds (clover?) in the depiction of the plot being sampled in Figure 8, page 54 of the submission.

D. Meteorological data:

Vero Beach, Florida: Daily reports of maximum and minimum temperature, as well as one additional observation (at 7:30 A.M. unless otherwise indicated; total participation; and wind speed expressed as anemometer dial reading and 24 hour movement.
Rutgers, New Jersey: Hourly readings of air temperature, relative humidity, dew point, time (expressed in 15 minute increments) in each hour during which leaves were wet, rainfall, and soil temperature (wind speed and direction were listed as categories, but "0's" were reported for every data point therein).
Stilwell, Kansas: Daily maximum and minimum temperature, as well as one additional observation (at 7:00 AM); total participation.

Meteorological, procedural and cultural factors may have contributed to this variability within and among sites.

At the New Jersey site, which had the least variable deposition levels, only 0.03 inches of rain, all by 0900 hours, were recorded on the day of application.

At the Kansas transferable residue plot, 1.11 inches of rain fell in the early morning on the day of, and before, MERIT was applied. It is not clear whether or not the exposure study in Kansas was conducted on the same Day 0 as the transferable residue study, but the applicant does state that "The moisture content of the soil on the MERIT Exposure Evaluation Plot in Kansas was less than on the MERIT transferable residue plot because it was covered by a large open-sided tent..." In addition, there may have been edge-effects (from rainfall) on the soil moisture levels along the inside perimeter of this open-sided tent (Note the shadow cast and position of the air monitors in Figure 17, page 62, of the submission.).

It was not possible to determine the rainfall immediately prior to application of MERIT in Florida because the start date of the experiment is neither provided nor can it be extrapolated from the given weather data. The applicant states that 3.3 inches of rain fell at the Florida site during the 14-day study period. However, there is no contiguous period of 14 days in the Florida weather summary where a cumulative total of 3.3 inches was reported.

E. Number of sites: The data were collected at three sites.

F. Number of replicates (total and per site): Three replicates were taken at each location for each sampling interval reported.

G. Application rate: The application rate was at the maximum label rate of 0.5 lb AI/acre of 21% LF MERIT. This is the curative rate; the label permits one application at this rate each season.

The theoretical target deposition level for MERIT, at the maximum turf application rate of 0.5 AI/acre, is 5.6 ug/cm^2. The apparent levels, recorded at three transferable residue plots (TRP) and one exposure evaluation plot (EEP), were as follows:

Site	Range (ug/cm^2)	Mean (SD)
Florida (TRP)	0.5-2.1*	1.4 (0.46)
New Jersey (TRP)	1.6-2.6*	2.2 (0.27)
Kansas (TRP)	2.6-4.1*	3.1 (0.69)
" (TRP)	1.3-3.0*	2.1 (0.77)
" (TRP)	2.5-5.5**	3.6 (1.15)
" (TRP)	1.8-3.9**	3.1 (0.95)
" (EEP)	2.3-5.5**	4.0 (1.21)

*Deposition Squares; **Absorbent Pads. N=9/treatment/site.

H. Mixing/loading/application procedures:
Vero Beach, Florida: The plots were treated using a John Deer 2350 tractor with a 20 ft ground-rig boom housing 13 nozzles spaced 18 inches apart and 19 inches above the ground. The spray equipment was calibrated using Miles Inc. SOP No, S-00220 to deliver 124.6 gallons/acre (GPA) at a nozzle pressure of 32 psi and a ground speed of 1 mph. Only 3 of the 13 spray nozzles (with a spray width of approximately 5.3 ft) were used to make the application. **Two passes** were made, one down each side of the 10 ft wide by 40 ft long turf plot. **Thus, a 7.2-inch overlap of spray potentially occurred in the center of the plot.** A mechanical agitator was run constantly in the spray tank.
Rutgers, New Jersey: The plot was treated using a Chem-Pro tractor with a 20 ft ground-rig boom using 12 nozzles spaced 20 inches apart and 24 inches above ground level. The sprayer was calibrated to deliver 114.6 GPA at a nozzle pressure of 15 psi and a ground speed of 1.5 mph. Only 5 of the 12 nozzles (with a spray width of approximately 5 feet) were used to make the application. **Two passes were made**, one down each side of the 10 ft wide by 40 ft long turf plot. A mechanical agitator was run constantly in the spray tank.
Stilwell, Kansas: The plot was treated with a Miller CO_2 motorized tractor sprayer with a 10 ft ground-rig boom housing 6 nozzles spaced 20 inches apart and 15 inches above ground. The spray equipment was calibrated to deliver 115 GPA at a nozzle pressure of 45 psi and a ground speed of 1 mph. The tractor was driven down the center of the plot to complete the application in a **single pass.** A mechanical agitator was run constantly in the spray tank.

The applicant states that such procedural differences as "variability in the sampling technique," may have been part of a combination of factors which contributed to the differences in transferable residues measured **between** treatment plots. It should be added that variability, both between and **within**, treatment plots could have been attributed, in part, to the method of application used at a particular site.

I. Number of applications: One application was made.

J. Intervals between applications: NA.

K. Sampling methodology: Nine application deposition squares (10 cm X 10 cm squares of cotton synthetic blend) were placed on each turf plot prior to MERIT application. During the residue trial in Florida and New Jersey, deposition squares were collected immediately after the spray had dried (approximately 1-2 hours post-application). During the trial in Kansas, 5 of the deposition squares were collected immediately after the application and 4 were collected immediately after the spray had dried (approximately 1-2 hours post-application). In addition, 9 absorbent pads (13.7 X 22 cm cellulose fiber media, 0.9 mm thick, manufactured by Gelman Sciences) were placed along side the deposition squares in the

residue trial in Kansas to determine if any MERIT losses were occurring due to penetration through the deposition squares. Five of the absorbent pad samples were collected immediately after application (those adjacent to the 5 deposition squares collected at this interval), and the remaining 4 absorbent pads were collected after the spray had dried.

Following collection, the deposition squares and absorbent pads were folded twice toward the exposed surface, placed in pre-labeled jars and sealed with teflon-lined screw cap lids. The samples were placed in coolers on dry-ice as soon as all replicates at a particular interval had been collected and sealed in jars. The coolers were then stored at -20°F freezer until they were transported by overnight express to Southwest Research Institute (SWRI) in San Antonio, TX for sample analysis.

The turf transferable residue samples were collected utilizing the PUF roller method designed by Hsu *et al* with various modifications described by Ross *et al*. The sampling procedure is described in Mile Inc. SOP No. PS-10. Briefly a 1600 cm^2 (1600 X 10 cm) piece of cotton/synthetic blend material (the same material used to construct the deposition squares and the whole-body dermal dosimeter garments) was used to construct a turf rolling sampling cloth (TRSC).

The transferable residue samples were collected by placing the TRSC on the treated turf and covering it with a 10 X 42 piece of 5 mil transparent plastic. A stainless steel roller core (identical to the one designed by Hsu *et al*.) was then rolled forward and backward along the length of the plastic-covered TRSC 10 times as described by Ross *et al*. Complete movement of the roller from one end of the cloth to the other and back constituted one roll. The roller was cleaned with ethanol prior to the collection of each sample.

The plastic covering was then removed and the TRSC was folded (exposed side against itself) several times and placed in a pre-labeled sample storage jar and sealed with a teflon-lined screw cap lid. Sample jars were placed in coolers on dry ice after all three replicates of a given interval had been collected. The coolers were stored in a -20_0F freezer until they were transported by overnight express to SWRI for sample analysis.

Three turf transferable residue samples were collected from each plot at each location on the following schedule: prior to application, as soon after the application as the spray had dried (approximately 2 hours post-application), 4 hours post-application, 12 hours post-application, and 1,2,3,5,7 and 14 days post-application. In addition to the transferable residue samples, 9 fortified transferable residue quality assurance (QA) samples (3 samples at 3 different fortification levels) and a control blank were prepared for MERIT at the 1, 7 and 14 day post-application intervals according to Miles Inc. SOP Nos. 0040 and 0041. QA samples were stored, transported and analyzed with the TRSC samples.

References Cited

Hsu, J.P., D.E. Camann, H. Schatterberg III, B. Wheeler, K. Villalobos, M. Kyle, S. Quarderer and R.G. Lewis. 1990. New Dermal Exposure Sampling Technique. Presented at the 1990 EPA/AWMA International Symposium "Measurement of Toxic and Related Air Pollutants, May 2, 1990, Raleigh, N.C.

Ross, J., T. Thongsinthusak, H.R. Fong, S. Magetich and R. Krieger. 1991. Potential Dermal Transfer of Surface Residue Generated from Indoor Fogger Use: Interim Report II. *Chemosphere* 22: 975-984.

L. Field/laboratory/storage recovery data: Field-generated concurrent recovery samples were either extracted in the same batch with, or immediately following, field samples generated at the same time. Laboratory-fortified concurrent recovery samples were generated with each batch of samples at a frequency of approximately one laboratory sample for every ten field samples, with at least one fortified sample per batch of field samples. Spiking levels varied by sample medium.

All samples were stored in a freezer maintained at a temperature below approximately -4°C. All field samples, with the exception of the dosimeter garments (See Part 2: Reentry Exposure Study), were extracted within ten days from the verified time of sample receipt (VTSR). Sample extracts (in methanol) were stored at a temperature of approximately -4°C. In most instances, extracts were analyzed within 30 days of the extraction date. **The maximum holding time was 64 days. During the method development phase of the project, the active ingredients were found to be stable in methanol for at least 58 days with no degradation of active ingredients.**

M. Data correction based on recoveries: The field and laboratory recovery data were included in this submission. **Storage recovery data were not included.**

N. Recent history of pesticide use at the sites: No information provided.

Summary of Standard Evaluation Procedure

A. Summary of review procedure used

1. Review of protocol relative to Subdivision K Reentry Guidelines: The report was examined to determine the extent to which it met the requirements of Subdivision K. Required elements include the following. A typical pesticide end-use product must be used. The site at which the study is conducted must be characterized by a

climate similar to those in which the product is likely to be used. The test substance must be applied in a manner consistent with the approved application methods specified for the end-use product and at the least dilution and highest permissible rate. The duration of the test must coincide with the time of year or season during which the product will likely be used to satisfactorily control the desired pest. The study must include meteorological data obtained at or near the location of the test site. Duplicate foliage samples must be collected periodically during the course of the study. Further, it is required that the first round of samples be taken as soon as feasible following the final application (i.e. when the dust has settled or the spray has dried). Sampling intervals should be short at first, and may increase with time. Storage of samples must take place only when necessary, and must be performed in such a way as to minimize residue dissipation. Finally, foliage residue must be reported in the units of ug/cm^2. of leaf surface.

2. Review of Quality Assurance/Quality Control Procedures: These procedures were reviewed to ensure that the data were collected in accordance with GLPs and requirements in Subdivision K and U, Applicator Exposure Monitoring, of the Pesticide Assessment Guidelines. Among these elements are: proper blanks and recovery spike samples, appropriate replicate samples, maintenance of sample identity and integrity, proper chain of custody and documentation procedures, and a description of the quality assurance of the investigation organization and analytical laboratory.

3. Verification of calculations: The raw data from the data sheets were followed to the raw data summary sheets, and through to the compiled data that was averaged for the purpose of statistical analysis. Peak heights given on chromatograms will be translated into mass volumes using the presented standard curves, and compared to the values given on the data sheets. For those chromatograms that correspond to residue samples, the calculations will be carried through to obtain a ug/cm^2 value for foliage samples, or ppm value for soil samples, and verified to be identical to the values presented by the author.

Study Evaluation Summary

A. Nature/purpose of study: This study was conducted by Miles Inc., Agricultural Division, Research and Development Department, to determine the levels, over time, of dislodgeable ("transferable") imidacloprid residue levels following the application of MERIT 21 LF on turf at the maximum label application

rate. This information would be used to generate compound specific turf transferable data for MERIT that could be used in conjunction with human exposure data to evaluate the potential risk to persons contacting treated turf.

B. Summary of results: The arithmetic mean, geometric mean and median deposited residues for all residue plots ranged from 1.4 to 3.8 ug/cm^2. These values are roughly equivalent to 25-68% of the theoretical target deposition rate for MERIT of 5.6 ug/cm^2. The arithmetic mean MERIT transferable residues immediately after the spray had dried ranged from 35.9 (+ or - 18.6) ng/cm^2 in Florida to 52.6 ng/cm^2 (+ or -35.9) in New Jersey and 150.8 (+ or - 30.2) ng/cm^2 in Kansas. These values represent 2.6, 2.4 and 5.6%, respectively, of the deposited residues measured during application. An exponential regression analysis was used to determine the half-life of MERIT for each turf plot and for the average of all three turf plots. For Florida, this value was approximately 2.0 days; for New Jersey, 0.9 days; and for Kansas, 1.0 days.

C. Adequacy of study protocol description: Satisfactory.

D. Adequacy of recovery data: Satisfactory. Recoveries for the field and laboratory spike samples were generally within the 80-120% range.

E. Acceptability of field and laboratory QA/QC procedures: Review of reported QA/QC procedures relative to U.S. EPA GLP and other QA/QA requirements and standards, such as outlined in Subdivision K, Reentry Protection and the Pesticide Assessment Guidelines, indicates that the field and laboratory procedures followed in this study are acceptable.

F. Adequacy of analytical techniques: Satisfactory.

G. Preliminary grade assignment/quality evaluation: Not determined.

H. Data gaps:

1. Recalculation of half-lives through the Day 7 collection point only (exclude Day 14). The plots were mowed and irrigated with one inch of water after transferable residue samples had been collected for that day. The half-life for the Florida site should also be calculated from the 4-hour through 7-day sampling period because 0.41 inches of rain fell between time 0 and 0 plus 4 hours.

2. Submission of representative confirmation chromatograms used to generate residue data cited in the study.

3. Submission of data used to confirm storage stability of samples.

J. Issues/items requiring submitter's clarification:

1. Clarification of the start date and of the rainfall recorded during the course of the study at the Florida site.

Part 2 - Reentry Exposure Study

Description of Study Protocol

A. Study identifier: 1994. Evaluation of Potential Exposure Resulting from Contact with MERIT-Treated Turf. Study Number: 92E043. Report Number: 106463. Authored by D.C. Eberhart and G. K. Ellisor, Miles Inc., Agricultural Division, Research and Development Department, 8400 Hawthorn Road, Kansas City, Missouri 64120-0013.

B. Geographical site description: Miles Research Park in Stilwell, Kansas. The test site was a 20 ft X 46 ft turf plot.

C. Crop Type: Kentucky Bluegrass. **The cultivar was not listed.**

D. Meteorological data: Daily maximum and minimum temperature, as well as one additional observation (at 7:00 AM); total participation.

E. Number of sites: One.

F. Number of replicates (total and per site): Ten replicate worker exposure determinations were made at the single study site.

G. Application rate: The application rate was at the maximum label rate of 0.5 lb AI/acre of 21% LF MERIT. This is the curative rate; the label permits one application per season at this rate.

H. Mixing/loading/application procedures: The plot was treated with a Miller CO_2 motorized tractor sprayer with a 10 ft ground-rig boom housing 6 nozzles spaced 20 inches apart and 15 inches above ground. The spray equipment was calibrated to deliver 115 GPA at a nozzle pressure of 45 psi and a ground speed of 1 mph. **Due to the positioning of tent poles at the test site, 5 passes across the width of the turf plot were necessary to properly complete the application.** A mechanical agitator was run constantly in the spray tank. The maneuvering challenges (and commensurate opportunities for overlaps and undersprays) created by this procedure are evident by the juxtaposition of the spray boom and tent pole in Figure 16 (page 61) of the submission.

I. Number of applications: One application was made.

J. Intervals between applications: NA.

K. Interval between application and reentry: As soon after the application as the spray had dried.

L. Monitoring methodologies (dermal and inhalation): Ten volunteer subjects performed a choreographed exercise (jazzercise) routine on the MERIT-treated exposure evaluation turf plot. An additional subject performed the same routine on an untreated control plot. The jazzercise routine was 20 minutes in length and was the same routine used previously by Ross *et al.* It involved continuous contact with the MERIT-treated turf (mostly from a prone position. Prior to the start of the study, the volunteer subjects were trained in the jazzercise routine by a certified jazzercise instructor. The training, consisting of 4 one-hour supervised practice sessions, was conducted to ensure that each subject was proficient before the start of the study. The jazzercise instructor performed her routine on an untreated plot next to the control subject's plot.

1. Passive dermal dosimetry: The dermal exposures of volunteer subjects performing the exercise routine on the MERIT-treated turf plot were measured by whole-body dosimetry. Each volunteer subject wore the following clothing during the exposure period as described by Ross *et al.* and Fong:

    1. Two pairs of white, cotton/synthetic blend footless tights (the lower dosimeter garments).
    2. Two long-sleeved, white, cotton/synthetic tee-shirts (the upper dosimeter garments).
    3. Two thin, white, 100% cotton gloves (Kodak cat. no. 187-771) on each hand.
    4. Two white, 100% cotton athletic ankle socks (FootLocker stock no. 16-634468-00-990) on each foot.

Prior to use, all dosimeter garments, gloves and socks were pre-washed with a brightener-free detergent and then pre-extracted with methanol and dichloromethane to remove partially interfering fluorescent whiteners. Before the start of the exposure monitoring period, each subject donned (with the assistance of study team members) the dosimeter garments over shorts and a tee shirt and wore them during the 20 minute jazzercise program. One set of dosimeter garments, one pair of gloves and one pair of socks were worn underneath the other.

The jazzercise routine began as soon after the application as the spray had dried. Immediately following the exposure period, the study team members removed the dosimeter garments, gloves and socks from each subject. Study team members wore lightweight surgical latex gloves during the removal of samples, and gloves were changed after handling each sample.

Each dosimeter garment (inside separate from outside) was placed in a pre-labeled glass jar, sealed with a teflon-lined lid and stored in a cooler on dry ice. Samples remained on dry ice or in a -20°F freezer until they were shipped via overnight express to the laboratory for analysis. In contrast, both outside gloves were sealed, stored, shipped and analyzed together as were two outside socks, the two inside gloves and the two inside socks.

A complete set of fortified field QA samples were prepared for each sampling period (5 samples at 3 different fortification levels) and were exposed to the same environmental conditions as the exposure samples during the 20 minute exposure monitoring period. These fortified field QA samples were prepared in the field and stored and transported with the exposure samples. All dermal exposure samples and corresponding fortified QA samples were analyzed by SWRI using reverse phase high pressure liquid chromatography.

2. Inhalation exposure: MERIT air concentrations were measured in the immediate vicinity of each volunteer subject during the performance of their exercise routine. The air samples were collected using 37 mm quartz microfibre (QMA) filters connected by polyvinylchloride tubing to portable industrial hygiene air sampling pumps. Each volunteer's air sampling apparatus was placed on the turf in the corner of his/her designated exercise area and the filter cassette was suspended 25 cm above the ground by taping the polyvinylchloride tubing to a wooden dowel rod. The air sampling pumps were turned on as soon as the exercise routine began and were turned off as soon as the routine was completed. The air sampling pumps were operated at a flow rate of 1 LPM and were calibrated before and after each sampling period according to Miles Inc. SOP PS-2. After collection, the pre-labeled filter cassettes were capped, sealed in Zip-Lock® bags and stored in coolers on dry ice or in a -20°F freezer until they were transported by overnight express to the laboratory for analysis. A complete set of fortified QA samples (5 samples at 3 different concentration levels) was prepared in conjunction with the inhalation exposure samples. All inhalation exposure samples and corresponding fortified QA samples were analyzed by SWRI using reverse phase high pressure liquid chromatography.

References Cited

Ross, J., T. Thongsinthusek, H.R. Fong, S. Magetich and R. Krieger. 1990. Measuring potential dermal transfer of surface pesticide residue generated from indoor fogger use: an interim report. Chemosphere 20: 349.360.

M. Clock times duration for monitored exposures: Twenty minutes.

N. Field/laboratory/storage recovery data: MERIT dosimeter garments were extracted 30 and 34 days following VTSR.

C. Data correction based on recoveries: Yes.

Summary of Standard Evaluation Procedure

(See Part 1: Foliage Dislodgeable Residue Study)

Study Evaluation Summary

A. Nature/purpose of study: This study was conducted by Miles Inc., Agricultural Division, Research and Development Department, to measure the inhalation and dermal exposure of persons performing a high contact activity on MERIT-treated turf and to calculate a turf-contact dermal transfer factor for MERIT which can be used in conjunction with product-specific transferable residue data to estimate similar exposures for other pesticides to turf.

B. Summary of results: The arithmetic and geometric mean MERIT **air concentrations measured in the immediate vicinity of the volunteer subjects** during performance of their exercise routine were approximately 6.6 (+ or - 2.6) and 6.2 (+ or - 1.5) ug/m^3, respectively. These air concentrations were greater than twice as high as the analytical limit of detection (2.5 ug/m^3) and **comparable to the air concentration measured in the immediate vicinity of the control subject** (6.5 ug/m^3).

The MERIT (ng/cm^2) measured by whole-body dosimetry for each volunteer subject was reported for each volunteer for inner upper dosimeter garments (IUDG), outer upper dosimeter garments (OUDG), inner lower dosimeter garments (ILDG), outer lower dosimeter garments (OLDG), inner gloves (IG), outer gloves (OG), inner socks (IS), outer socks (OS) and whole-body. These values were obtained by dividing the measured amount of MERIT on each dosimeter sample (ng) by the calculated skin surface area (cm^2) for each representative anatomical region.

The whole-body surface for each adult volunteer was estimated from the height and weight formula in EPA's Exposure Factors Handbook (EPA 1989), and the percentage of whole-body surface area represented by each anatomical region was estimated from EPA's Subdivision (U EPA 1987).

Whole-body surface areas for 10-year old and 5-year old children were estimated from the height and weight formula of Haycock et al. based on the 50^{th} percentile height and weight for both sexes in each age group. The estimated MERIT dermal exposures (ug) for two clothing scenarios are reported for the adult volunteer subjects, 10-year-old children and 5-year old children.

The two clothing scenarios are referred to as a minimum clothing scenario (MCS) and a typical clothing scenario (TCS). The

MCS assumes that short pants and a sleeveless shirt are worn and the TCS assumes that short pants, a sleeveless shirt and shoes are worn. The estimated MERIT dermal exposures for MCS are 1,566.7 ug, 919.5 ug and 681.7 ug for adult subjects, 10-year-old children and 5-year-old children, respectively. The corresponding exposure estimates for the TCS are 989.5 ug, 539.9 ug, and 413.7 ug, respectively. These estimates are based on the exposures measured in this study for adults performing a 20 minute exercise routine and the relevant surface area adjustments discussed above for the two clothing scenarios. Dermal exposure rates (ug/hr) were calculated based on the following three assumptions:

1. The maximum amount of time available for children to play outdoors on pesticide-treated turf is 4 hours/day.
2. The minimum amount of contact that could occur with the pesticide-treated turf during a 4-hour play period is equal to the amount of contact that occurred during the 20-minute exercise routine evaluated in this study.
3. The maximum amount of contact that could occur with the pesticide-treated turf during a 4-hour period is equal to 4 times the amount of contact that occurred during the 20-minute exercise routine evaluated in this study.

The upper-bound range of dermal exposure rates are 247.4-1,566.7 ug/hr, 135.0-919.5 ug/hr and 103.4-681.7 ug/hr for adult volunteer subjects, 10-year-old children and 5-year-old children, respectively. The upper-bound range of dermal exposure doses are 14.1-89.5 ug/kg/day for adult volunteer subjects, 19.4-131.8 ug/kg/day for 10-year-old children and 22.1-145.8 ug/kg/day for 5-year-old children. Comparing these dermal exposure doses (ug/kg/day) to the no observable effect level (NOEL) of 1,000 mg/kg/day established in a 15-day (6 hours/day X 5 days/week) dermal toxicity in rabbits results in margins of safety (MOS) of 11,173-70,922, 7,587-51,546, and 6,859-45,249 for adult volunteer subjects, 10-year-old children and 5-year-old children, respectively.

Estimated minimum and maximum turf-contact dermal transfer factors (cm^2) for both clothing scenarios was also calculated. These were derived by dividing the appropriate dermal exposure rate (for MCS or TCS) by the MERIT transferable residue level (0.074 ug/cm^2) measured on the exposure evaluation plot just prior to the start of the exercise routine. Based on these calculations, the upper-bound range of turf-contact dermal transfer coefficients is 3,343-21,172 cm^2/hr of adults, 1,824-12,426 cm^2/hr for 10-year-old children and 1,397-9,212 cm^2 for 5-year-old children.

The estimated minimum and maximum turf-contact dermal transfer factors (cm^2/hr) for both clothing scenarios were used in conjunction with the 15-day dermal NOEL (ug/kg/day), the average body weight for each age group (kg) and a 100-fold safety factor to

calculate an upper-bound range of safe residue levels (ug/cm^2) for MERIT on turf. For adults, the estimated safe residue levels for MERIT on turf range form 8.3-52.3 ug/cm^2. The estimated safe residue levels for MERIT on turf for 10-year-old children range form 5.6-38.2 ug/cm^2 and for 5-year-old children from 5.1-33.5 ug/cm^2.

References Cited

Haycock, G.B., B.J. Schwartz, and D.H. Wisotsky. 1978. Geometric method of measuring body surface area: a height-weight formula in infants, children, and adults. Journal of Pediatrics 93: 62-66.

United States Environmental Protection Agency (EPA). 1989. Exposure Factors Handbook. Office of Health and Environmental Assessment. Washington, DC. EPA/600/8-89/043.

United States Environmental Protection Agency (EPA). 1987. Pesticide Assessment Guidelines. Subdivision U.

C. Adequacy of study protocol description: Satisfactory.

D. Adequacy of recovery data: Satisfactory.

E. Acceptability of field and laboratory QA/QC procedures: Review of reported QA/QC procedures relative to U.S. EPA GLP and other QA/QA requirements and standards, such as outlined in Subdivision K, Reentry Protection and the Pesticide Assessment Guidelines, indicates that the field and laboratory procedures followed in this study are acceptable.

F. Adequacy of analytical techniques: Satisfactory.

G. Preliminary grade assignment/quality evaluation: Not determined.

H. Data gaps: None.

I. Issues/items requiring submitter's clarification: None.

Attachments (2)
cc: L. LaSota, OREB
Correspondence File
Chemical File

13544

R131640

Chemical: Imidacloprid

PC Code: 129099
HED File Code: 13000 Tox Reviews
Memo Date: 11/14/1996
File ID: *DPD223275*
Accession #: 000-00-0108

HED Records Reference Center
8/29/2006